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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,622	02/19/2002	Wolfgang Daum	14005.01	5614

22865 7590 02/17/2005
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EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,622

Applicant(s)

DAUM ET AL.

Examiner

Glenn K Dawson

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ad

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07-27-2002, 9.1.02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,5,6,8,10 and 13-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Doscher, et al.-6786904.

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Doscher discloses a method of placing a stent into a body lumen and non-invasively heating the stent using Rf energy at 50 Hz –2MHz, which creates an electromagnetic field received by the stent which heats the stent and inductively heats the surrounding tissue. The heating of the stent causes a drug in a coating of the stent to be released upon heating and melting of the coating. See col. 4 lines 1-3; col. 4 lines

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61-67, col. 5 lines 1-2; col. 7 lines 14-28; col. 7 lines 52-57; col. 8 lines 25-41 and col. 15 lines 2-6.

Claims 1-7, 10, 13-15 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tu, et al.-6179789.

Tu discloses a metallic stent heated by Rf energy between 50-2000kHz. The stent has a drug present in a coating that is released upon heating. See col. 2 lines 4-38; col. 3 lines 6-21 and 65-66; col. 4 lines 32-34; col. 6 lines 22-28

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doscher, et al.-'904 in view of Tu-'789.

Doscher discloses the invention as claimed with the exception of the specific mechanism for drug release or activation. Tu discloses the placing of a drug in a carrier coating that when heated by the stent causes the release, activation and increased diffusion of the drug. It would have been obvious to have used a drug delivery mechanism such as that taught by Tu in the device and method of Doscher, et al.- as this has been shown to be effective at controllably delivering a needed drug to a specific area of the vasculature.

Claims 1-8, 10 and 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naghavi, et al.-6451044 in view of Doscher, et al.-'904.

Naghavi discloses the heating of a stent by Rf energy to treat vascular problems such as restenosis. The stent is coated with a drug that is released upon the heating of the stent. See col. 11 lines 52-65; col. 19 lines 31-36; col. 21 line 66-col. 22 line 3; col. 27 lines 59-65. However, the specific frequency is not disclosed. Doscher discloses the heating of a stent using the claimed frequency. It would have been obvious to have used the frequency taught by Doscher, as this frequency has been shown to be

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effective at heating the stent while reducing the demand for power and thus the complexity of the power supply system see col. 10 lines 25-46.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doscher, et al.-'904 or Naghavi, et al.-'044.

Both of these references disclose the stent as claimed with the exception of the heat deactivating the drug instead of activating it. The applicant stated on pages 2-3 that the German prior art reference disclosed that the opposite effect of deactivating the drug upon heating could also be accomplished by varying the carrier or drug. As it was known at the time of the invention to provide a heat releasable drug coating on a stent which is activated upon heating by body temperature, the examiner contends that one skilled in the art would have recognized that at some point it might be necessary to stop the medicating to prevent overmedication, and therefore providing a non-invasive means by which to control (stop) the drugs elution into the tissues would have been beneficial and obvious. Therefore using a stent to both deliver and stop drug delivery at specific temperatures using a controlled electromagnetic field exterior to the body would have been an obvious modification to either reference.

Information Disclosure Statement

The German Patent DE 29519982 cited in the specification and on the 1449 of 04-01-02 has only been considered for the information in the figures, as no English translation of this document has been received.

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 10-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
17 February 2005